K063391

ATTACHMENT 11

510(k) Summary of Safety and Effectiveness

This 510(K) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart 807.87(h), 807.92(e).

1) Identification of Submitter

APR 26 2007

Sapheneia Commercial Products AB
Teknikringen 8
SE-583 30 Linköping, Sweden

2) Official Correspondent

Hans Grahn, Ph.D.
Vice President of International Growth & Development
Sapheneia Commercial Products AB
Teknikringen 8
SE-583 30 Linköping, Sweden
Phone: +46-8-6072417
Cell: +46 73 801 1995
Fax: +46-8-6072417
hgrahn@saphenia.org

Date of Submission
01/24/07

3) Identification of Product

Device Trade Name:	Sapheneia Clarity™
Release Version:	1.1
Common Name:	Image Enhancement System
Classification Name:	Picture Archiving and Communications System
Reference:	Per 21 CFR 892.2050
Class:	II
Review Panel:	Radiology
Product Classification:	90 LLZ, Picture Archiving and Communications System
Guidance document:	Guidance for the submission of Premarket notifications for medical image management system (issued on July 2000)
Manufactured by:	Sapheneia Commercial Products AB
Distributed by:	Sapheneia Commercial Products AB

"I certify that, in my capacity as President, of Sapheneia Commercial Products AB, I will make available all information included in this Premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the Premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the Premarket notification submission, including any adverse safety and effectiveness information, but excluding all

patient identifiers, and trade secret and confidential information, as defined in 21 CFR 20.61."

4) Indications for Use:

The Sapheneia Clarity is intended for use by radiologists for transfer, storage, noise reduction, contrast enhancement and viewing of multi-modality images from a variety of diagnostic systems. The device is also intended to be used by trained/qualified technologists for installation and maintenance of the software. For your legal protection, it is strongly recommended that you backup your original data.

For digital mammography, only DICOM 'For Presentation' images should be displayed for primary image diagnosis

5) Device Description

The Sapheneia Clarity™ image processing software reduces noise and enhances contrast of relevant structures to increase image quality through structure adaptation, tissue adaptation, scale adaptation, and noise adaptation. Sapheneia Clarity™ employs a sophisticated statistical analysis of the image structure in the neighborhood of each pixel. Using robust estimation methods the dominant structures are separated from the embedding noise. Once the structure has been determined, it is possible to strengthen the interesting parts while simultaneously reducing the noise. The acquisition remains the same, i.e. the image processing can be generated from multiple modalities and with predefined or specific acquisition protocol settings.

The workflow of Sapheneia Clarity™ image enhancement system can be easily adapted to existing radiology departmental workflow. Sapheneia Clarity™ acts as a DICOM node that receives DICOM3.0 digital medical image data from the modality or another DICOM source, processes the data and then forwards the enhanced and/or original study to the selected destination. This destination can be any DICOM node, typically either the PACS system or a specific workstation.

6) Marketing History

The software has not yet been marketed.

7) Marketed Devices - Predicate Devices

Insofar as it relates to safety, the Sapheneia Clarity™ is substantially equivalent to the currently marketed and to other legally marketed post-processing software products that analyzes data from medical images. Specifically, intended use, design, and function and performance characteristics for Sapheneia Clarity™ are substantially equivalent to the predicate device named **ContextVision AB,** SharpView Image Enhancement System **(K024028).**

ContextVision AB, SharpView Image Enhancement System **(K024028)** is an image transfer, enhancement, and viewing analysis package intended for use for the visualization and enhancement of medical images. Thus, insofar as DICOM images are concerned, ContextVision AB SharpView Image Enhancement System is substantially identical to the Sapheneia Clarity™. Safety and effectiveness, comparison to predicate device, thus far the functionality of the Sapheneia Clarity™ is substantially identical to certain of the functions provided by ContextVision AB SharpView Image Enhancement System, though again, there may be slight difference in image filtration as a result of differences in the underlying algorithms. It is the opinion of Sapheneia Commercial Products AB, that Sapheneia Clarity™ raises no new issues of safety and effectiveness as compared to the predicate devices.

raises no new issues of safety and effectiveness as compared to the predicate devices.

The Sapheneia Clarity™ provides image enhancement, and in the opinion of Sapheneia Commercial Products AB, this medical device is substantially equivalent to the SharpView Image Enhancement System (K024028), ContextVision AB, Storgatan 24, SE-582 23 Linköping, Sweden.

8) Performance Testing

The Sapheneia Clarity™ will successfully complete integration testing, beta testing and verification prior to market release.

9) Performance Standards

The Sapheneia Clarity has been designed to conform to the DICOM3.0 standard and the JPEG standard. The use of the Sapheneia Clarity™ is compatible with various off-the-shelf hardware components. Those monitors recommended by the Company will meet the SMPTE test pattern standard.

10) Software

Software development for the Sapheneia Clarity™ system follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the qualification results. Appropriate steps have been taken to control all identified risks for this type of image display and qualification product.

11) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the Sapheneia Clarity™ software in the "Operator's Manual".

12) Conclusion

The Sapheneia Clarity™ software is designed and manufactured to meet United States and international standards for the post processing and image enhancement system of images acquired from multi modality devices.

The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verifications and validation testing processes. The system has been shown to be substantially equivalent to the predicate devices, and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Rick Mancilla
CEO
Sapheneia LLC
932 North State Street
JACKSON MS 39202-2613

APR 26 2007

Re: K063391
Trade/Device Name: Sapheneia Clarity™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 3, 2007
Received: April 9, 2007

Dear Mr. Mancilla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 12

Indication(s) for Use Statement

510(k) Number (if known): K063391

Device Name: Sapheneia Clarity™

Indications for Use:

The Sapheneia Clarity is intended for use by radiologists for transfer, storage, noise reduction, contrast enhancement and viewing of multi-modality images from a variety of diagnostic systems. The device is also intended to be used by trained/qualified technologists for installation and maintenance of the software. For your legal protection, it is strongly recommended that you backup your original data.

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Prescription Use ✓ AND/OR Over-The-Counter Use____

(Per 21 C.F.R. 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063391